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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/904,182

07/11/2001

Albert C. Lardo

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07/24/2008

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EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

07/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/904,182 | Applicant(s) LARDO ET AL. | |
| | Examiner david shay | Art Unit 3735 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 7, 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-67,69-84 and 86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-67,69-84 and 86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). This will correct claim misnumbering which has existed since the amendment filed April 12, 2006.

Misnumbered claims 68 (first occurrence), 68 (second occurrence), and 69-85 have been renumbered 68-86. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The dependencies of all claims will also be changed in a similar manner, so for example, renumbered claims 70-74 will depend from claim 69, rather than cancelled claim 68.

The rejections based on Sinofsky et al are hereby withdrawn on view of applicant's arguments. The following rejections, based on Pless are now applied to the claims. While Pless appears also to not be prior art in view of the filing date of the provisional application upon which it is based, July 31, 2000, evidentiary submissions Filed May 7, 2004 show the claimed subject matter therein to have been in the possession of Pless prior to the filing date of applicant's provisional application. It is noted that the claimed invention of Pless encompasses: (claim 1) subjecting cardiac tissue containing a photodynamic drug to a light source arranged so as to produce a lesion in a pattern corresponding to a light source such that the non-target tissue is not exposed to light; (claim 2, dependent on claim 1) introducing said photodynamic drug to said cardiac tissue; (claim 4, dependent on claim 2) wherein said introducing step comprises local introduction of said photodynamic drug to said cardiac tissue; (claim 6, dependent on claim

1) wherein said predetermined pattern encircles the pulmonary vein bed in the left atrium of a patient having said cardiac tissue; (claim 7, dependent on claim 1) wherein said predetermined pattern encircles at least one os of superior pulmonary veins in the left atrium of a patient having said cardiac tissue; (Claim 10 dependent on claim 1) wherein said predetermined pattern is interior to the heart containing said cardiac tissue.

Claims 61-63 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pless in combination with Diederich et al. Pless teaches ablating the os of the pulmonary vein using photodynamic therapy as set forth above. Diederich et al teach employing a balloon to direct various types of energy, including light to a specific area in the os of a pulmonary vein to produce a lesion that will form a conduction block and infusing contrast agent. It would have been obvious to the artisan of ordinary skill to employ the phototherapeutic treatment of Pless in the method of Diederich et al, since Diederich et al teach that many methods may be used to produce the lesion, or to employ the guidance and imaging techniques of Diederich et al, in the method of Pless, since this is a known method for positively engaging the os of the pulmonary vein for ablation, as shown by Diederich et al and to administer the photosensitizer via perfusing the coronary arteries, or by intravenous injection, since these are not critical; do not require site specific administration of the photosensitizer; and provide no unexpected result, thus producing a method such as claimed.

Claims 64-67, 69-78, and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pless in combination with Diederich et al as applied to claims 61-63 and 84 above, and further in combination with Leone. Leone teaches, a porous balloon constructed from a semi-permiable membrane which is inflated with and thereby delivers a photosensitizer to the tissue

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with which it is in contact, the balloon also houses an optical fiber which emits light to activate the photosensitizer. It would have been obvious to the artisan of ordinary skill to employ the phototherapeutic treatment balloon of Leone in the combined method of Pless and Diederich et al, since this would apply the photodynamic sensitizer directly to the tissue of interest, or to employ the pulmonary vein ablation technique of the combined method of Pless and Diederich et al in the method of Leone, since this would prevent arrhythmia, as taught by both Pless and Diederich et al, thus producing a method such as claimed.

Claims 79-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pless in combination with Diederich et al as applied to claims 61-63 and 84 above, and further in combination with Swanson. Swanson teaches, in addition to transmitting the energy, which can be laser light through a balloon, a guidance technique, which can include MRI; the energy application, which can include transmission of the tissue destroying energy through intervening media in contact with the tissue, to which the energy is essentially transparent; the application to atrial fibrillation; and incorporates by reference U.S. Patent No. 5,636,634, which discloses the infusion of saline or an anticoagulant. It would have been obvious to the artisan of ordinary skill to employ the phototherapeutic treatment of the combined method of Pless and Diederich et al in the method of Swanson, since this causes less trauma to the tissue, or to employ the guidance technique of Swanson, which can include MRI; the energy application, which can include transmission of the tissue destroying energy through intervening media in contact with the tissue, to which the energy is essentially transparent; and the application to atrial fibrillation in the method of Pless combined with Diederich et al, since this would assure that the application of

energy was done in the proper place, and also be determinative of the proper endpoint for the procedure, thus producing a method such as claimed.

Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pless in combination with Diederich et al, as applied to claims 61-63 and 84 above, and further in combination with Rice et al. Rice et al teach that phthalocyanines are appropriate photosensitizers. It would have been obvious to the artisan of ordinary skill to employ phthalocyanines as the photosensitizers, since these are effective as photosensitizers and Pless teaches no particular photosensitizer, thus producing a method such as claimed.

Applicant's arguments with respect to claims 61-67, 69-84 and 86 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/
Primary Examiner, Art Unit 3735